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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,916	10/02/2000	Carl Anthony Blau	UOFW115624	4343

26389 7590 02/10/2005

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,916	BLAU ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) *43,54,67-69 and 77-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42,44-53,55-66,70-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and the second declaration under 37 CFR 1.132 by Dr. Blau have been entered. Claims 1-88 are pending in the instant application. This application contains claims 43, 54, 67-69, and 77-88 drawn to an invention nonelected without traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-42, 44-53, 55-66, and 70-76 are currently under examination. An action on the merits follows.

Those sections of Title 35, US code, not included in this action can be found in a previous office action.

Claim Rejections - 35 USC § 102

The rejection of claims 1-42, 44-53, 55-66, and 70-76 under 35 U.S.C. 102(e) as being anticipated over U.S. Patent No. 5,741,899 (4/21/98), hereafter referred to as Capon et al., is maintained. Applicant's arguments and the second declaration by Dr. Blau under 37 CFR 1.132 have been fully considered but have not been found persuasive in overcoming the instant grounds of rejection for reasons of record as discussed in detail below.

It is noted that the election of species by applicants of "hematopoietic stem cells", made without traverse in the response received on 8/30/02, still stands. The claims have only been examined to the extent that they read on the elected species.

The applicant reiterates their previous argument that Capon et al. does not provide an enabling disclosure for making and using primary hematopoietic stem cells containing a construct encoding a fusion protein comprising at least one signaling domain and at least one drug-binding domain, citing *Elan Pharm., Inc. v. Mayo Foundation for Medical and Education Research*. Applicant's reason for considering the Capon et al. disclosure non-enabling is that Capon et al. states in column 42, lines 61-64, while describing a method to detect proliferation of cells transfected with the fusion protein comprising FKBP, that the cells are added to culture dishes coated with saturating concentrations of FK1012. It is applicant's position that by teaching "saturating" concentrations, Capon does not provide an enabling disclosure. In response, please note that applicant's argument regarding "saturating" concentrations of FK1012 do not apply to the composition claims, claims 44-53, and 55. These claims are drawn to genetically engineered primary cells which contain a DNA encoding the fusion protein of the instant invention. Capon et al. clearly teaches and provides specific working examples of these genetically engineered cells. Further, the intended use of the cells in the product claims does not have patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In regards to the method claims, the office disagrees with the applicant's assertion that the use of "saturating" concentrations would prevent proliferation. According to the applicant, and the second Blau declaration, saturating concentrations of FK1012 would not induce proliferation because by occupying all the FKBP sites, dimerization is prevented, citing Fuh et

al.. The second Blau declaration also provides additional data which the applicant states was obtained in 1997 which shows that F1Flt3-containing BA/F3 cells do not show growth relative to 1% WEHI conditioned media at high concentrations of FK1012. Regarding Fuh et al., Fuh et al. was concerned with the design of antagonists to the human growth hormone receptor. Fuh et al. does not provide any teachings or statements regarding the binding activity of FK1012 to FKBP. Further, Fuh et al. actually shows that while extremely high concentrations of hGH would decrease proliferation, proliferation was still seen (Fuh et al., Figure 2). While Fuh et al. states that **maximal** cell proliferation may require less than total receptor occupancy, Fuh et al. does not teach that total receptor occupancy would inhibit any level of proliferation. In fact, the negative effects on proliferation observed by Fuh et al. were at concentrations far in excess of the "saturating" concentration of hGH. The word "saturate" means to cause to combine till there is no further tendency to combine (see for instance the Merriam-Webster Dictionary). The word "saturate" does not mean to deliver concentrations far in the excess of the amount required to bind all the sites. Thus, Fuh et al. does not support applicant's argument that the teachings of Capon et al. are non-enabled.

In regards to the data presented in the second Blau declaration, it is noted that the data was generated using cells which express a fusion protein comprising 1 FKBP domain and the Ftl3 signaling domain. While it appears that high concentrations of FK1012 did not stimulate the growth of these cells compared to cells cultured with 1% WEHI conditioned media, it is noted that this example is not analogous to the examples in Capon. Capon et al. used fusion proteins with 3 tandem FKBP domains, thus providing more binding sites for FK1012. The fusion proteins described by Capon et al. are in fact most similar to those exemplified in the Blau et al.

(1997) publication discussed in the previous office action. The fusion proteins in the Blau et al. publication comprise 3 tandem FKBP and the EpoR signaling domain. The Blau et al. publication, on page 3078, Col. 1, states that at higher concentrations of FK1012, less proliferation is observed than at the optimal concentration which is 100nM. "Less proliferation" in this context, however, is still substantial. Figure 2 on page 3078 of Blau et al. provides a dose/proliferative response curve for cells transduced with the FKBP fusion proteins and treated with FK1012. At the highest concentrations, 1000 nM, proliferation is somewhat less than at 100 nM, but it is still substantially higher than baseline. Therefore, for fusion proteins comprising 3 tandem FKBP, as taught by Capon et al., the Blau et al. publication shows that high concentrations of FK1012 are in fact successful in stimulating proliferation of cells containing the fusion protein. The applicant is further reminded that the claims as written provide no limitation as to the concentration of the drug, and that the specification further does not provide any teachings as to the concentration of drug required to stimulate proliferation. As such, applicant's arguments and the second Blau et al. declaration are not found persuasive. Therefore, for the reasons provided above and in previous office actions, the rejection of record is maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 9:30-6:00 EST. If the examiner is not available, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735. For all official communications, **the new technology center fax number is (571) 273-8300**. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER